K090256

510(K) SUMMARY

JUL - 6 2009

Submitter: DavisMade, Inc.
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Flint, MI 48506
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info@standingdani.com (e-mail)

FDA Registration #: 1833039

Contact Person: Daniel Davis

Preparation Date: 27 January 09

Proprietary name: Power Standing Dani

Classification Name: Electric Power Wheelchair, Stand-up

Regulatory Class: Class II

Product Code: IPL

Identification of Predicate Devices: Lifestand - *LSC Lifestand (*K041535)
DavisMade Standing Dani (K890602)
Ulrich Alber *e-fix* ® power add-on
(K041535)\

Intended Use: The Power Standing Dani stand-up wheelchair is a sit to stand mobility device equipped with power driven rear mounted wheels intended for the pediatric population with disabilities which limits their ability to ambulate without assistance. The product is designed for indoor/outdoor use on normal pedestrian terrain such as asphalt, grass, and gravel and not indicated for slopes exceeding 6° in a downhill, uphill or lateral orientation. The device is not intended for use while being transported in a moving vehicle.

Device Description: The Power Standing Dani stand-up wheelchair (wheelstand) is equipped with a vertical positioning prone board with an attached standing platform, inclined slightly forward, to which the pediatric is supported with lateral, anterior and posterior components in the upright position. The prone board and standing platform are comprised of positioning components that are interchangeable and whose location can be adjusted to accommodate the precise needs for each individual. The prone board and attached standing platform are securely mounted to an adjustable steel base

frame, to which the power driven rear wheels and front suspension caster wheels are mounted.

The drive power is provided through a rear mounted wheel system, branded as the e-fix® is supplied by Ulrich Alber. Gmbh. Each of the two drive wheels contains a 110 Watt motor, brake and gear box in its hub. The wheels sizes are available in 12" or 24" diameter. The wheel motors are powered with 2x12V (12Ah or 17Ah) batteries, which are secured in a solid mounting rack. Front suspension castor wheels support the front of the frame and allow indirect steering by applying differential power to the rear drive wheels through the joystick controller.

Safety and Effectiveness: The Power Standing Dani was developed based on extensive knowledge and experience gained by providing standing mobility for pediatrics requiring assistive technology since the introduction of the Manual Standing Dani® in 1990. This knowledge and experience has shown prone standing with adjustable support systems, allows the pediatrics optimum psychological and physiological benefits.

The manually propelled Standing Dani, however, is not intended for those pediatrics with restrictive strength and physical attributes that limit their ability to be independently mobile. The addition of a safe and effective joy stick controlled power drive add-on provides that pediatric population the same psychological and physiological benefits as those capable of manually self-propelling.

The Power Standing Dani utilizes the identical prone board and standing platform as the Manual Standing Dani and incorporates an FDA cleared wheelchair power add-on conversion kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2009

DavisMade, Incorporated
% Mr. Daniel W. Davis
Chief Executive Officer & Founder
2511 Davison Road
Flint, Michigan 48506

Re: K090256
Trade/Device Name: The Power Standing Dani
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup Wheelchair
Regulatory Class: II
Product Code: IPL
Dated: April 17, 2009
Received: June 16, 2009

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: _____
(If known)

Indications for use: The Power Standing Dani stand-up wheelchair (wheelstand) is a sit to stand mobility device equipped a removable prone board and standing platform with a joystick controlled power driven rear mounted wheels, providing the pediatric population with disabilities the assistive technology to independently ambulate in the standing position. Types of disability diagnosis include spina bifida, cerebral palsy, muscular dystrophy, spinal muscular atrophy, spinal cord injury, and various other neurological disorders.

Proprietary name: Power Standing Dani

Prescription Use XX _____ Over-The Counter Use

(Per 21 CFR 801 Subpart D) OR (21 CFT 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090256